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EXAMINER	
SIM, YONG H	

ART UNIT	PAPER NUMBER
2629	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/803,080	CUNNINGHAM ET AL.	
	Examiner	Art Unit	
	Yong Sim	2629	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-32 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is /are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 11/16/2004 and 7/30/2007.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. **Claims 1, 4 – 6, 8 – 11, 13 – 16, 18 – 25 and 28 – 31 rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al. (Hereinafter "Anderson" US 2004/0009459 A1).**

Re claim 1, Anderson teaches a device, comprising: an interface member ("Manikin" Fig. 13) including a material (See Fig. 13 for materials inside of the manikin.); a manipulandum ("Needle" Fig. 13) movable in a degree of freedom (See Fig. 13, the needle is movable in x, y and z axis.), the manipulandum configured to penetrate the material (See fig. 13); a sensor configured to output a position signal based on the position of the manipulandum (Para 0165; "the position of the needle is detected through an encoder and the positioning sensor"); and an actuator configured to output haptic feedback by applying a compressive force to the material based on the position

signal (Para 0166; "forces are encoded and transferred to the servo motor that controls the friction resistance between the force wheel and the needle.").

Re claim 4, Anderson teaches the device of claim 1, wherein the interface member includes a simulated bone structure (Para 0174; "performs a simulated vertebroplasty on the simulated bony structure.").

Re claim 5, Anderson teaches the device of claim 1, wherein the material includes a first layer having its own density and a second layer having its own density different from the density of the first layer, the manipulandum configured to penetrate the first layer and the second layer of the material (Para 0174; "the user inserts the needle attached to the simulated syringe into a selected site surface on the manikin which comprises various insertion site. The user advances the needle through various body tissues including skin, muscle, fat and bone/a plurality of layers.")

Re claim 6, Anderson teaches the device of claim 1, wherein the actuator is a clamp coupled to the interface member (See fig. 14. The baffle is a clamp which clamps the needle between the wheels.).

Re claim 8, Anderson teaches the device of claim 1, the actuator being a first actuator, the device further comprising a plurality of actuators including the first actuator, each actuator from the plurality of actuators being an individually actuatable

clamp (Para 0174; "a selected site surface on the manikin which comprises various insertion site locations along the back of the manikin over the spinal region." The manikin comprises various insertion locations with various actuators which are clamps as can be seen in Fig. 13).

Re claim 9, Anderson teaches a device, comprising: a manipulandum ("The structure that the Needle is attached to" Fig. 13 or the robotic arm in Fig. 12) movable in a degree of freedom (See Fig. 13, the needle is movable in x, y and z axis.); a sensor configured to output a position signal based on a position of the manipulandum (Para 0165; "the position of the needle is detected through an encoder and the positioning sensor"); a retainer ("Manikin or the clamp structure including the baffle and the wheels" Fig. 13) defining an interior in which a material is disposed (See fig. 13), the material configured to receive an object moved by the manipulandum; and an actuator coupled to the retainer (See fig. 13), the actuator configured to output haptic feedback via the retainer based on the position signal (Para 0166; "forces are encoded and transferred to the servo motor that controls the friction resistance between the force wheel and the needle.").

Re claim 10, Anderson teaches the device of claim 9, wherein the manipulandum includes a first portion (Frame, Fig. 13) and a second portion (Sheathe, Fig. 13), the second portion configured to be removably coupled to the object ("Needle" Fig. 13).

Re claim 11, Anderson teaches the device of claim 9, wherein the manipulandum is configured to move in a rotary degree of freedom about an axis, and move simultaneously along the axis (See Para 0164. The robotic arm with six degrees of freedom is controlled by a user's manipulation which can rotate and move simultaneously along an axis.).

The limitations of claim 13 are substantially similar to the limitations of claim 4. Therefore, it has been analyzed and rejected substantially similar to claim 4.

Re claim 14, Anderson teaches the device of claim 9, wherein the retainer is configured to compress the material in response to actuation of the actuator (See Fig. 13. The baffle and the material in response to the actuation of the servo motor.).

Re claim 15, Anderson teaches the device of claim 9, wherein the retainer is configured to modify a density of the material based on the position signal (Para 0166; "forces are encoded and transferred to the servo motor that controls the friction resistance between the force wheel and the needle. The resistance forces are calculated from the physical properties/different densities of the tissue around the needle").

Re claim 16, Anderson teaches the device of claim 9, wherein the retainer is a clamp having an opening, the actuator including a motor configured to modify a size of

the opening based on the position signal (See Fig. 13, when the servo motor activates to turn the servo wheel, the baffle compresses the wheels to change the size of the opening for the needle.).

Re claim 18, Anderson teaches the device of claim 9, further comprising: a guide ("Sheathe" Fig. 13) configured to receive at least a portion ("Needle" Fig. 13) of the manipulandum, the guide being removably coupled adjacent to the retainer (See fig. 13).

Re claim 19, Anderson teaches the device of claim 9, wherein the manipulandum is movable in two degrees of freedom (Para 0156; "Each end of the curved frame is placed in a channel of a support which it can slide along in and rotate.")

Re claim 20, Anderson teaches the device of claim 9, wherein the manipulandum is movable in a rotary degree of freedom and a linear degree of freedom (Para 0156; "Each end of the curved frame is placed in a channel of a support which it can slide along in and rotate.").

Re claim 21, A device, comprising: a manipulandum ("The structure that the Needle is attached to" Fig. 13 or the robotic arm in Fig. 12); a sensor configured to output a position signal associated with a position of an object ("Needle" fig. 13)

engaged by the manipulandum, the position signal being based on a position of one of the manipulandum and the object (Para 0165; "the position of the needle is detected through an encoder and the positioning sensor"); a retainer ("Manikin or the clamp structure including the baffle and the wheels" Fig. 13. Or See Fig. 16 for an air controlled retainer.) defining an interior in which a material is disposed, the material configured to receive at least a portion of the object (See fig. 13); and an actuator coupled to the retainer, the actuator configured to output haptic feedback by varying a density of the material via the retainer based on the position signal (Para 0166; "forces are encoded and transferred to the servo motor that controls the friction resistance between the force wheel and the needle.").

The limitations of claim 22 are substantially similar to the limitations of claim 15. Therefore, it has been analyzed and rejected substantially similar to claim 15.

Re claim 23, the device of claim 21, wherein the retainer is a housing configured to vary the density of the material (See fig. 16. The retainer is a housing using a controllable air pressure mechanism to provide force feedback to vary the density of the material. Also see Para 0014)

Re claim 24, Anderson teaches an interface member for use with a haptic feedback device including a manipulandum ("The structure that the Needle is attached to" Fig. 13 or the robotic arm in Fig. 12) movable in a degree of freedom, the interface

member configured to be penetrated by the manipulandum (See fig. 13), a sensor configured to output a position signal based on the position of the manipulandum (Para 0165; "the position of the needle is detected through an encoder and the positioning sensor"), and an actuator coupled to the interface member and configured to apply a compressive force based on the position signal (Para 0166; "forces are encoded and transferred to the servo motor that controls the friction resistance between the force wheel and the needle."), the interface member comprising: a material portion (See fig. 16), the material portion configured to be penetrated by at least a portion of the manipulandum, the material portion being subject to the compressive force by the actuator in response to the position signal (Para 0014).

The limitations of claim 25 are substantially similar to the limitations of claim 4. Therefore, it has been analyzed and rejected substantially similar to claim 4.

The limitations of claim 28 are substantially similar to the limitations of claim 5. Therefore, it has been analyzed and rejected substantially similar to claim 5.

Re claim 29, Anderson teaches a device, comprising: a body member including a membrane; an interface material coupled adjacent the membrane (Para 0174; "the user inserts the needle attached to the simulated syringe into a selected site surface on the manikin which comprises various insertion site. The user advances the needle through various body tissues including skin/membrane, muscle, fat and bone/a plurality of

layers.") ; a first guide defining a channel therethrough, the first guide configured to be inserted in the body member through the membrane at a first location (See fig. 13); a second guide defining a channel therethrough, the second guide configured to be inserted in the body member through the membrane at a second location (See Fig. 15 for the syringe which is within the attached spinal needle. Para 0174); a manipulandum configured to be removably inserted in at least one of the first guide and the second guide (See Fig. 13); a position sensor configured to output a position signal based on a position of the manipulandum; and an actuator coupled to the interface material and configured to output haptic feedback via the haptic feedback member based on the position signal (Para 0166; "forces are encoded and transferred to the servo motor that controls the friction resistance between the force wheel and the needle.").

Re claim 30, Anderson teaches a method, comprising: receiving a position signal associated with a position of a manipulandum (Para 0165; "the position of the needle is detected through an encoder and the positioning sensor"), at least a portion of the manipulandum penetrating the interface material (See fig. 13); and outputting haptic feedback by varying a density of the interface material based on the position signal (Para 0166 "FIG. 14, shows an enlarged view of the needle portion of the device and its interaction with encoders of the interface which allow the position of the needle to be continuously tracked. A force wheel in proximity to the needle implements haptic feedback in response to signals received by a system processor.").

Re claim 31, Anderson teaches the method of claim 30, wherein the varying the density includes applying a compressive force to the interface material via an actuator (See Fig. 13, when the servo motor activates to turn the servo wheel, the baffle compresses the wheels to change the size of the opening for the needle.).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claims 7 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of van Oostrom et al. (Hereinafter "Oostrom" US 6,921,267 B2).**

Re claim 7, Anderson teaches the device of claim 1, wherein the actuator is an air controlled actuator (See fig. 16)

But does not expressly teach wherein the actuator is a vacuum coupled to the interface member.

However, Oostrom teaches a simulated lung for use in a real time simulated medical procedure comprising a vacuum pressure source and a positive pressure source.

Therefore, taking the combined teachings of Anderson and Oostrom, as a whole, it would have been obvious to a person having ordinary skill in the art to incorporate the idea of using the vacuum source to control the pressure of a simulated body part as taught by Oostrom into the device comprising an actuator which is air controlled to obtain a device comprising an air controlled actuator for the surgery simulation wherein a vacuum source is used to accurate simulate the density changes of the simulation model.

The limitations of claim 32 are substantially similar to the limitations of claim 7. Therefore, it has been analyzed and rejected substantially similar to claim 7.

6. **Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson.**

Re claim 12, Anderson teaches the device of claim 9.

But does not expressly recite a simulated pedicle of a vertebrae.

However, as Examiner acknowledges that it is well known in the art that vertebroplasty procedure as described by Anderson is performed for the treatment of disease involving pedicle of a vertebrae.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use a simulated pedicle of a vertebrae for performing a simulated vertebroplasty procedure in order to achieve more realistic hand-eye coordination.

7. **Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Delp et al. (Hereinafter "Delp" US 5,682,886).**

Re claim 17, Anderson teaches the device of claim 9.

But does not expressly teach wherein the manipulandum is a screwdriver and the object is a screw.

However, Delp teaches a computer-assisted surgical system wherein a simulation jig is provided comprising a screw and a screwdriver to insert into bones (Delp: Col. 19, lines 53 - 60).

Therefore, taking the combined teachings of Anderson and Delp, as a whole, it would have been obvious to a person having ordinary skill in the art to incorporate the idea of using a screw and a screw driver for a surgery simulation as taught by Delp into the device of Anderson to obtain a device comprising a manipulandum wherein the manipulandum comprises a screwdriver and a screw to simulate a bone surgery while

providing haptic feedback to give the operator more realistic feel for the surgery simulation.

8. **Claims 2 - 3 and 26 - 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Madsen et al. (Hereinafter "Madsen" US 6,318,146 B1).**

Re claim 2, Anderson teaches the device of claim 1.

But does not expressly describe the material that includes a plurality of beads.

However, Madsen teaches medical phantom body part material comprising beads suitable for various parts of the body (Madsen: Col. 5, lines 1 – 16).

Therefore, taking the combined teachings of Anderson and Madsen, as a whole, it would have been obvious to a person having ordinary skill in the art to incorporate the idea of having beads for a phantom or a model of human body parts into the device as taught by Anderson to obtain a device comprising an actuator wherein the compress the model bone structures made from beads to vary the density of the bone for surgery simulation.

Re claim 3, Anderson teaches the device of claim 1.

But does not expressly describe the material that includes a plurality of beads.

However, Madsen teaches medical phantom body part material comprising beads suitable for various parts of the body (Madsen: Col. 5, lines 1 – 16).

Therefore, taking the combined teachings of Anderson and Madsen, as a whole, it would have been obvious to a person having ordinary skill in the art to incorporate the idea of having beads for a phantom or a model of human body parts into the device as taught by Anderson to obtain a device comprising an actuator wherein the compress the model bone structures made from beads to vary the density of the bone for surgery simulation.

The combined teachings of Anderson and Madsen teach a device comprising compressible beads.

But does not expressly teach polystyrene beads.

However, Examiner acknowledges that specifying the type of material for the beads is not a required design feature, but is one feature out of many alternative design features, it is an obvious matter of design choice to have polystyrene beads.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use polystyrene beads to give the simulation model added flexibility and durability.

The limitations of claim 26 are substantially similar to the limitations of claim 2. Therefore, it has been analyzed and rejected substantially similar to claim 2.

The limitations of claim 27 are substantially similar to the limitations of claim 3. Therefore, it has been analyzed and rejected substantially similar to claim 3.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Sim whose telephone number is (571) 270-1189. The examiner can normally be reached on Monday - Friday (Alternate Fridays off) 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amr Awad can be reached on (571) 272-7764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

YHS
1/21/2008

AMR A. AWAD
SUPERVISORY PATENT EXAMINER